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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,539	02/08/2002	Kevin B. Morton	NEOMTRX.4C1DV3	3961

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KNOBBE MARTENS OLSON & BEAR LLP  
2040 MAIN STREET  
FOURTEENTH FLOOR  
IRVINE, CA 92614

EXAMINER

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/072,539

Applicant(s)

MORTON ET AL.

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

- A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 02 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 45-59 is/are allowed.
- 6) ☐ Claim(s) 1-15, 17-28 and 30-43 is/are rejected.
- 7) ☐ Claim(s) 16, 29 and 44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 16, 29 and 44 are objected to because of they depend from rejected claims.

### ***Claim Rejections - 35 USC § 112***

2. Rejections under 35 U.S.C. 112, second paragraph, have been withdrawn due to amendment.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1 – 15, 17 – 28 and 30 – 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Covington et al. (US 6517513 B1).

Applicant claims a method for obtaining a sample of intraductal fluid, the method comprising providing an intraductal fluid sampling device having an adjustable support, at least one inflatable bladder carried by the support and a patient interface surface carried by the bladder; adjusting the support to fit a breast to be tested; placing the interface in contact with the breast; inflating the bladder to compress the breast; and non-invasively obtaining the fluid sample. The adjusting step occurs before the contacting step or the placing step occurs before the adjusting step. The adjusting step comprises adjusting the support to fit the breast without compression or rotating an adjustment ring. The placing step comprises contacting the interface surface with the breast such that at least a portion of the bladder may impart compression to the lactiferous sinus. The inflating step comprises compressing the lactiferous sinus; compressing the breast at least partially on the anatomically proximal aspect to the lactiferous sinus; or inflating the bladder with a heated fluid wherein the heated fluid is from about 102 – 120F. The inflating step comprises inflating the bladder in cycles lasting about 1 – 30 seconds or 5 – 20 seconds, in a series of cycles of about 3 – 60 cycles per minute or about 4 – 20 cycles per minute. Finally, the inflation cycles are controlled by a control circuit.

Covington teaches methods and devices for obtaining a sample of intraductal fluid, wherein a device is used to aspirate the fluid (col.11-12). The device comprises an adjustable

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support, an interface with one or more compression elements to facilitate fluid removal, wherein the device may fit the use (or is adjusted to fit the breast to be tested) (col.13). The compression (inflating) is achieved by multiple annular rings, which allows peristaltic motions (col.13). The compression element may comprise inflatable structures (or bladders) that may further contain water or gel, specifically a heated gel (col.13). A microprocessor (or control circuit) is used to control pumping and compression cycles (col.13).

Covington does not teach the method with the claimed inflation cycles, fluid temperatures or compression locations. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to optimize such variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the variables of Covington with a reasonable expectation for successfully obtaining breast intraductal fluid.

***Allowable Subject Matter***

6. Claims 16, 29 and 44 appear to be allowable if written in independent form. Claims 45 – 59 also appear to be allowable over the prior art.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad  
June 27, 2003



LEON B. LANKFORD, JR.  
PRIMARY EXAMINER